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U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

REQUEST UNDER 37 C.F.R. 1.607 FOR DECLARATION OF AN INTERFERENCE

ATTORNEY DOCKET NO.: 01662/50308

Application Number	Filing Date	Examiner	Art Unit
09/997,126	November 29, 2001	Sonya N. Wright	1626

Invention Title: NOVEL CRYSTAL FORMS OF ATORVASTATIN HEMI-CALCIUM AND PROCESSES FOR THEIR PREPARATION AS WELL AS NOVEL PROCESSES FOR PREPARING OTHER FORMS

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Date: July 28, 2004

Signature: Kathy Fall

Sir:

The Applicants respectfully request declaration of an interference between claims 147-155 of the present patent application and:

(1) claim 6 of U.S. Patent No. 6,605,729 to Byrn et al.,
(2) claim 6 of U.S. Patent Application Serial No. 10/456,046 by Byrn et al. (published March 18, 2004 as 2004/0054193), and
(3) claim 2 of a U.S. patent application1 filed June 2, 2004 in the name of Van der Schaaf et al. as a continuation of U.S. Patent Application Serial No. 10/130,197.

1. No fee is believed to be due for this submission. Should any fees be required, please charge such fees to **Kenyon & Kenyon, LLP** Deposit Account No. **11-0600**.

2. The Commissioner is also authorized to charge any additional fees or credit any overpayment to the deposit account of **Kenyon & Kenyon**, Deposit account No. **11-0600**.

3. A copy of this sheet is enclosed.

Dated: JULY 28, 2004 By: Joseph A Coppola

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	Aronhime et al.
Serial No.	:	09/997,126
Filing Date	:	November 29, 2001
For:	:	NOVEL CRYSTAL FORMS OF ATORVASTATIN HEMI-CALCIUM AND PROCESSES FOR THEIR PREPARATION AS WELL AS NOVEL PROCESSES FOR PREPARING OTHER FORMS
Examiner	:	Sonya N. Wright
Art Unit	:	1626

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REQUEST UNDER 37 C.F.R. §1.607 FOR DECLARATION OF AN INTERFERENCE

Sir:

The Applicants respectfully request declaration of an interference between claims 147-155 of the present patent application and:

(1) claim 6 of U.S. Patent No. 6,605,729 to Byrn *et al.*,

(2) claim 6 of U.S. Patent Application Serial No. 10/456,046 by Byrn *et al.* (published March 18, 2004 as 2004/0054193), and

(3) claim 2 of a U.S. patent application[1] filed June 2, 2004 in the name of Van der Schaaf *et al.* as a continuation of U.S. Patent Application Serial No. 10/130,197.

[1] The serial number of this patent application is not yet available.

For the reasons set forth below, an interference exists and should be declared.

I. Identification of the interfering patent and applications

U.S. Patent No. 6,605,729 ("the Byrn patent") issued to Byrn *et al.* from U.S. Patent Application Serial No. 10/184,669 on August 12, 2003 and is assigned on its face to Warner-Lambert Co., Morris Plains, NJ. It was filed on June 28, 2002 and claims the priority of U.S. Provisional Application Serial No. 60/302,049 filed June 28, 2001 under 35 U.S.C. §119(e). Accordingly, the potential effective filing date of the Byrn patent is June 28, 2001.

U.S. Patent Application Serial No. 10/456,046 ("the Byrn application") was filed by Byrn *et al.* on June 6, 2003 and is assigned on its face to Warner-Lambert Co., Ann Arbor, MI. This application is a continuation of the Byrn patent. Claim 6 of this application is exactly the same as claim 6 of the Byrn patent. Therefore, for the sake of simplicity, only claim 6 of the Byrn patent is discussed below. However, it should be understood that when reference is made to claim 6 of the Byrn patent, such reference applies equally to claim 6 of the Byrn application.

A U.S. patent application ("the Van der Schaaf application") was filed on June 2, 2004 with inventors Van der Schaaf *et al.* as a continuation of U.S. Patent Application Serial No. 10/130,197, which was filed on October 7, 2002 as a national phase application of International Publication No. WO 02/051804, which was filed on December 19, 2001. The Van der Schaaf application claims the priority of European Patent Application No. 822,249.2, filed December 27, 2000, under 35 U.S.C. § 365. Accordingly, the potential effective filing date of the Van der Schaaf application is December 27, 2000.

II. Prima facie case of priority by Applicants

The present application is an original utility application filed November 29, 2001. It claims the benefit of priority under 35 U.S.C. §119(e) to a chain of provisional applications including U.S. Provisional Patent Application Serial No. 60/250,072, filed November 30, 2000; U.S. Provisional Patent Application Serial No. 60/267,897, filed February 9, 2001; U.S. Provisional Patent Application Serial No. 60/281,872, filed April 5, 2001; U.S. Provisional Patent Application Serial No. 60/312,144, filed August 13, 2001; and U.S. Provisional Patent Application Serial No. 60/326,529, filed October 1, 2001.

It will be seen below that claims 147-155 are supported by the first-filed provisional application, No. 60/250,072, and all later-filed provisional applications in the chain in the manner provided by 35 U.S.C. § 112. Accordingly, Applicant's effective filing date is November 30, 2000. Applicants' effective filing date is prior to the June 28, 2001 potential effective filing date of the Byrn patent and the Byrn application (by more than six months) as well as the potential December 27, 2000 effective filing date of the Van der Schaaf application. Therefore, there is a basis upon which the present application is entitled to a judgment relative to the Byrn patent, the Byrn application, and the Van der Schaaf application and no separate *prima facie* showing by affidavit under 37 C.F.R. § 1.608(b) is required.

III. Presentation of the proposed count

Pursuant to 37 C.F.R. 1.607(a)(2), Applicants propose the following count:

> **Count**
>
> Crystalline atorvastatin hemi-calcium and solvates thereof characterized by a powder X-ray diffraction pattern generated using CuK_α radiation with peaks at 4.8, 5.2, 8.0, 9.2, 9.6, 19.0, 20.0, 24.0 and 29.0 ± 0.2 degrees two-theta

The proposed count corresponds exactly to claim 148 of the present application, except that the proposed count has been re-written in independent form.

IV. Claim 6 of the Byrn patent corresponds substantially to the proposed count

"A claim of a patent or application that is designated to correspond to a count but is not identical to the count is said to correspond substantially to the count." 37 C.F.R. § 1.601(f). Claim 6 of the Byrn patent should be designated as corresponding to the count since that claim corresponds substantially to the count. Claim 6 of the Byrn patent reads as follows:

> 6. A crystalline Form X atorvastatin or a hydrate thereof having an X-ray powder diffraction containing the following 2θ values measured using CuK_α radiation: 4.7, 5.2, 5.8, 6.9, 7.9, 9.2, 9.5, 10.3 (broad), 11.8, 16.1, 16.9, 19.1, 19.8, 21.4, 22.3 (broad), 23.7 (broad), 24.4, and 28.7.

Claim 6 corresponds to the count because claim 6 is directed to the same crystalline form of atorvastatin as the count and thus is directed to the same patentable invention as the count. This form is called Form VIII in the present application and Form X in the Byrn patent. Claim 6 and the count are directed to the same crystalline form even though slightly different words are used by claim 6 and the count to define this crystalline form. As explained below, the different words merely reflect slightly different ways of referring to the peaks in the powder x-ray diffractogram of the crystalline form and are thus merely slightly different ways of defining the same patentable invention.

Pursuant to 37 C.F.R. § 1.607(a)(4), Applicants explain in detail below why claim 6 corresponds to the proposed count although the count is not a *verbatim* copy of claim 6.

A. <u>The recitation in claim 6 "A crystalline Form X of atorvastatin or a hydrate thereof . . . " corresponds substantially to the proposed count</u>

Claim 6 is directed to "a crystalline Form X of atorvastatin or a hydrate thereof." The term "Form X" is merely a name given by Byrn *et al.* to the interfering subject matter and is not a substantive limitation of the claim.

Although claim 6 does not expressly recite that Form X atorvastatin is a hemi-calcium salt as set forth in the count, the Byrn specification makes evident that it is.

The abstract of the Byrn patent states that Form X and all the other forms of "atorvastatin" disclosed are atorvastatin hemi-calcium salts.

The only "Form X atorvastatin" enabled by the Byrn patent is a hemi-calcium salt. There are three preparations of Form X in the Byrn patent prepared by methods designated as "Method A," "Method B," and "Method C." *See* col. 27, line 54 to col. 28, line 4. In Methods A and B, Form X was made by slurrying amorphous "atorvastatin calcium" in isopropanol/water. In Method C, a "saturated solution of amorphous atorvastatin calcium in isopropanol/water (9:1) was stirred for 2 days, filtered, and air dried to afford crystalline Form X atorvastatin." Other than the calcium component of the atorvastatin calcium starting material, no metal was added to the reaction mixture in any of the three preparations. Therefore, the Form X product is the calcium salt.

The Form X product of Methods A, B, and C is reported to have a melting point of 180.1°C. The product is not atorvastatin lactone because atorvastatin lactone has a melting

point of 159.2-160.7°C, which is much lower than that of the product (Merck online database available through *Chemical Abstracts* online database). In addition, the water content of the product is consistent with Form X being atorvastatin hemi-calcium and is inconsistent with it being a lactone. The Byrn patent characterizes the product of Methods A, B, and C as follows:

> "Crystalline Form X atorvastatin, mp 180.1° C., trihydrate Karl Fisher 5.5% (3.5 mol of water)."

(col. 27, line 54 to col. 28, line 4)

This characterization of Form X means that the product contains 5.5 weight percent of water (which can be measured directly using the Karl Fisher technique). The mole ratio of water to the organic component is calculated to be 3.5:1 from this weight percent. If one postulates that Form X obtained by Methods A, B, and C of the Byrn patent is atorvastatin hemi-calcium having a molecular weight of 1155.34 g/mol., then a measured 5.5 wt. % water content would correspond to a mole ratio of 3.73 water to atorvastatin hemi-calcium (according to Applicants' calculations) which is in reasonable agreement with the 3.5 mole ratio reported in the Byrn patent. However, if one postulates that Form X obtained by Byrn was atorvastatin lactone having a molecular weight of 540.24 g/mol., then a measured 5.5 wt. % water would correspond to a mole ratio of only 1.7, or about half of the water content reported by Byrn. Therefore, applicants submit that the Byrn patentees reported that the product was a trihydrate because they knew that the product was atorvastatin hemi-calcium and not some other salt or atorvastatin lactone.

Since the Byrn patent teaches no way to make Form X other than by slurrying or stirring a saturated solution of amorphous atorvastatin calcium, Applicants respectfully submit that the Byrn patent would not enable the full scope of claim 6 under 35 U.S.C. §112 if the term "Form X atorvastatin" were construed to cover a crystal form of atorvastatin lactone or a salt of another metal.

For these reasons, "A crystalline Form X atorvastatin or hydrate thereof" of claim 6 has substantially the same meaning as "Crystalline atorvastatin hemi-calcium and solvates thereof" of the count.

B. The recitation in claim 6 that Form X has ". . . an X-ray powder diffraction containing the following 2θ values measured using CuK_α radiation: 4.7, 5.2, 5.8, 6.9, 7.9, 9.2, 9.5, 10.3 (broad), 11.8, 16.1, 16.9, 19.1, 19.8, 21.4, 22.3 (broad), 23.7 (broad), 24.4, and 28.7" corresponds substantially to the count

Claim 6 recites that Form X has peaks in its powder X-ray diffraction ("PXRD") pattern at "4.7, 5.2, 5.8, 6.9, 7.9, 9.2, 9.5, 10.3 (broad), 11.8, 16.1, 16.9, 19.1, 19.8, 21.4, 22.3 (broad), 23.7 (broad), 24.4, and 28.7" °2θ. This listing of peaks in claim 6 corresponds substantially to the count. Table 1 below compares the peaks in claim 6 of the Byrn patent to the peak positions of the count, including the error range given in the count.

Table 1

Proposed Count	Byrn Patent Claim 6
4.6-5.0	4.7
5.0-5.4	5.2
	5.8
	6.9
7.8-8.2	7.9
9.0-9.4	9.2
9.4-9.8	9.5
	10.3 (broad)
	11.8
	16.9
18.8-19.2	19.1
19.8-20.2	19.8
	21.4
	22.3 (broad)
23.8-24.2	23.7
28.8-29.2	28.7

Each of the nine two-theta value ranges of the count has a corresponding peak in claim 6 of the Byrn patent except for the 23.8-24.2°2θ and 28.8-29.2°2θ ranges ("the un-met ranges"). For each of the un-met ranges there is a peak in claim 6 that is only 0.1°2θ outside of the range, specifically at 23.7 and 28.7 °2θ. The Applicants submit that, when measurement uncertainties are taken into account, the peaks at 23.7 and 28.7°2θ in Byrn claim 6 correspond substantially to the 23.8-24.2°2θ and 28.8-29.2°2θ ranges of the count.

The occurrence of measurement errors in the recording of PXRD patterns is recognized and discussed in the Byrn patent. According to the Byrn patent, calibration errors, instrument errors, sample height differences, operator errors, and preferred orientation (collectively "measurement errors") can cause peaks to shift sometimes even as much as 1 degree. (col. 17, line 7 to col. 18, line 22). Some of these shifts can be corrected by applying a correction factor to PXRD patterns obtained on different machines, which, it is said, will bring the peak positions into agreement within 0 to 0.2°2θ of each other. Accordingly, the Byrn patent acknowledges that peak positions recorded on different instruments can differ from each other by as much as 1°2θ and may still differ by as much as 0.2°2θ even after applying a correction to the data. Therefore, the 0.1° 2θ discrepancy between the 23.7 and 28.7 values in Byrn claim 6 and the count can be attributed to measurement errors and do not make Form X as defined by claim 6 substantially different from the invention defined by the proposed count.

Claim 6 recites additional peak positions at 5.8, 6.9, 10.3, 11.8, 16.9, 21.4 and 22.3 °2θ that are not contained in the count. Those peak positions do not define a different crystalline form and thus do not define a separately patentable invention because they are inherent in the crystalline form of atorvastatin hemi-calcium having peaks within the 2θ value ranges specified by the count (*i.e.*, the form referred to as Form VIII in the present application and Form X in the Byrn patent). The inherent presence of these peaks in Form VIII can be seen in Figure 1. Figure 1 is an overlay of the PXRD pattern of Form VIII of the present invention ("Aronhime Form VIII") that appears in Fig. 3 of the present application and the PXRD pattern of Byrn Form X that appears in Fig. 6 of the Byrn patent.

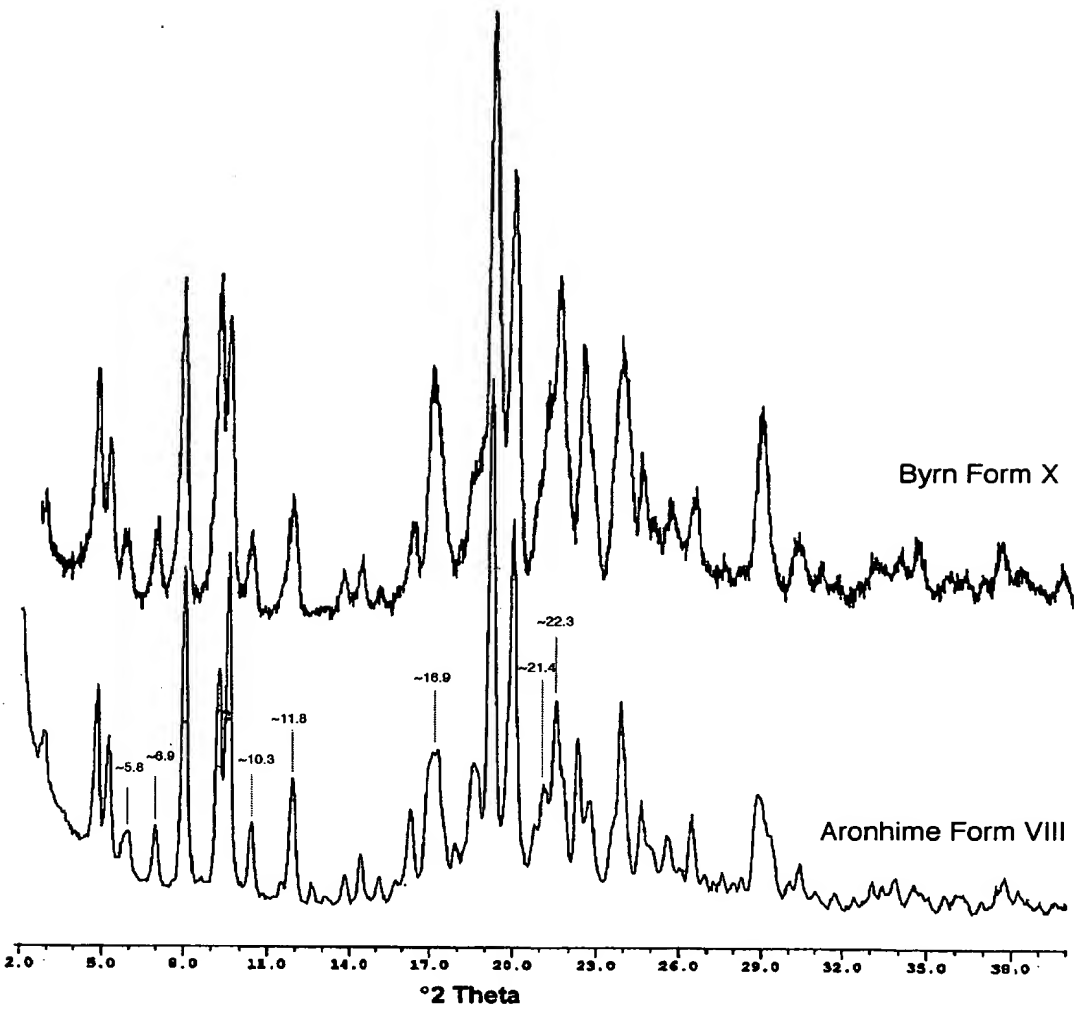

Figure 1

As pointed out in Figure 1, Aronhime Form VIII does, in fact, have peaks at about 5.8, 6.9, 10.9, 11.8, 16.9, 21.4 and 22.3 °2θ. Moreover, those peaks are referred to in the present application, where they are said to appear at 5.9, 7.0, 10.4, 11.9, 17.1 (broad), 21.6 and 22.4±0.2°2θ. (present application, p.3, ¶ [0044]).

The inherency of these peaks in Aronhime Form VIII and Byrn Form X can be appreciated when one considers that all other known forms of atorvastatin hemi-calcium have different X-ray diffraction patterns and thus fail to meet the limitations of the count. Only Aronhime Form VIII and Byrn Form X correspond to the count (either exactly or substantially) and both inherently possess peaks at the positions recited in Byrn claim 6.

Therefore, because Aronhime Form VIII and Byrn Form X both have peaks at the additional peak positions designated in claim 6 of the Byrn patent and because no other crystalline form of atorvastatin calcium corresponds to the count, the additional limitations of claim 6 are inherent in the subject matter of the count. Since the additional limitations of claim 6 are inherent in the subject matter of the count, claim 6 defines the same patentable invention as the count and corresponds substantially to the count.

V. Claim 2 of the Van der Schaaf application corresponds substantially to the proposed count

Claim 2 of the Van der Schaaf application should be designated as corresponding to the count because claim 2 is directed to the same crystalline form of atorvastatin as the count and thus is directed to the same patentable invention as the count. Claim 2 of Van der Schaaf reads as follows.

> 2. A crystalline polymorph of [R-(R*,R*)]-2-(4-fluorophenyl)-beta,delta-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid calcium salt which exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in d-values (Å) at 31.0 (vw), 18.6 (m), 17.0 (w), 15.3 (vw), 12.8 (w), 11.2 (m), 9.6 (s), 9.3 (w), 8.6 (w), 7.4 (m), 6.5 (vw), 6.2 (vw), 5.47 (w), 5.21 (m), 4.64 (vs), 4.46 (s), 4.14 (m), 3.97 (m), 3.74 (m), 3.62 (vw), 3.38 (w), 3.10 (m);
> wherein (vs) = very strong intensity; (s) = strong intensity; (m) = medium intensity; (w) = weak intensity; (vw) = very weak intensity.

Pursuant to 37 C.F.R. § 1.607(a)(4), Applicants explain why claim 2 corresponds to the proposed count although the count is not a *verbatim* copy of claim 2.

A. The recitation in claim 2 "A crystalline polymorph of [R-(R*,R*)]-2-(4-fluorophenyl)-beta,delta-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid calcium salt" corresponds substantially to the count

The phrase "crystalline polymorph of [R-(R*,R*)]-2-(4-fluorophenyl)-beta,delta -dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid calcium salt" in claim 2 has the same meaning as "crystalline atorvastatin hemi-calcium" in the count. Claim 2 uses the systematic name of the compound whose trivial name is atorvastatin. According to the specification of the Van der Schaaf application, the subject matter of claim 2, which is designated Form A in the Van der Schaaf application, is a 2:1 calcium salt, which the present application refers to as a hemi-calcium salt (p. 2, 1st and 2nd full paragraphs). For these reasons, the phrase "crystalline polymorph of [R-(R*,R*)]-2-(4-fluorophenyl)-beta,delta -dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid calcium salt" corresponds substantially to the count.

B. **The recitation in claim 2 that Form A "exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in d-values (Å) at 31.0 (vw), 18.6 (m), 17.0 (w), 15.3 (vw), 12.8 (w), 11.2 (m), 9.6 (s), 9.3 (w), 8.6 (w), 7.4 (m), 6.5 (vw), 6.2 (vw), 5.47 (w), 5.21 (m), 4.64 (vs), 4.46 (s), 4.14 (m), 3.97 (m), 3.74 (m), 3.62 (vw), 3.38 (w), 3.10 (m); wherein (vs) = very strong intensity; (s) = strong intensity; (m) = medium intensity; (w) = weak intensity; (vw) = very weak intensity" corresponds substantially to the count**

Claim 2 characterizes the claimed subject matter by the position and approximate intensities of peaks in its PXRD pattern. The peak positions are expressed in terms of *d*, the interplanar spacing between the reflecting planes, in angstrom units. The interplanar spacing is related to the angle of reflection θ by the Bragg equation: $\sin(\theta)=n*\lambda/2d$. Lambda (λ), the wavelength of the reflected radiation, is 1.5418 Å for the CuK_α line used to generate the PXRD patterns in the interfering applications and patent. Parameter "n" is an integer. Table 2 shows the positions of the peaks recited in claim 2 in units of degrees two-theta (converted using the Bragg equation) and associates them with a peak position of the count, including the error range given in the count.

Table 2

Proposed Count	Van der Schaff Claim 2
	2.85
4.6-5.0	4.75
5.0-5.4	5.20
	5.78
	6.91
7.8-8.2	7.89
9.0-9.4	9.21
9.4-9.8	9.51
	10.3
	12.3
	13.6
	14.3
	16.2
	17.0
18.8-19.2	19.1
19.8-20.2	19.9
	21.5
	22.4
23.8-24.2	23.8
	24.6
	26.4
28.8-29.2	28.8

Each of the nine two-theta value ranges of the count has a corresponding peak in claim 2 of the Van der Schaaf application. Since the peak values recited in the count define a unique crystalline form of atorvastatin, this indicates that the count and claim 2 of the Van der Schaaf application are directed to the same crystalline form, and thus the same patentable subject matter. Those peak values recited in claim 2 but not in the count are therefore inherent in this crystalline form and their recitation in claim 2 does not make claim 2 refer to a separately patentable invention from that of the count.

To illustrate the identity of the subject matter defined by the count and by claim 2 of the Van der Schaaf application, the Applicants have constructed the following Fig. 2, which compares the PXRD of Form A atorvastatin from the Van der Schaaf application and Form VIII from the present invention (upon which the count is based).

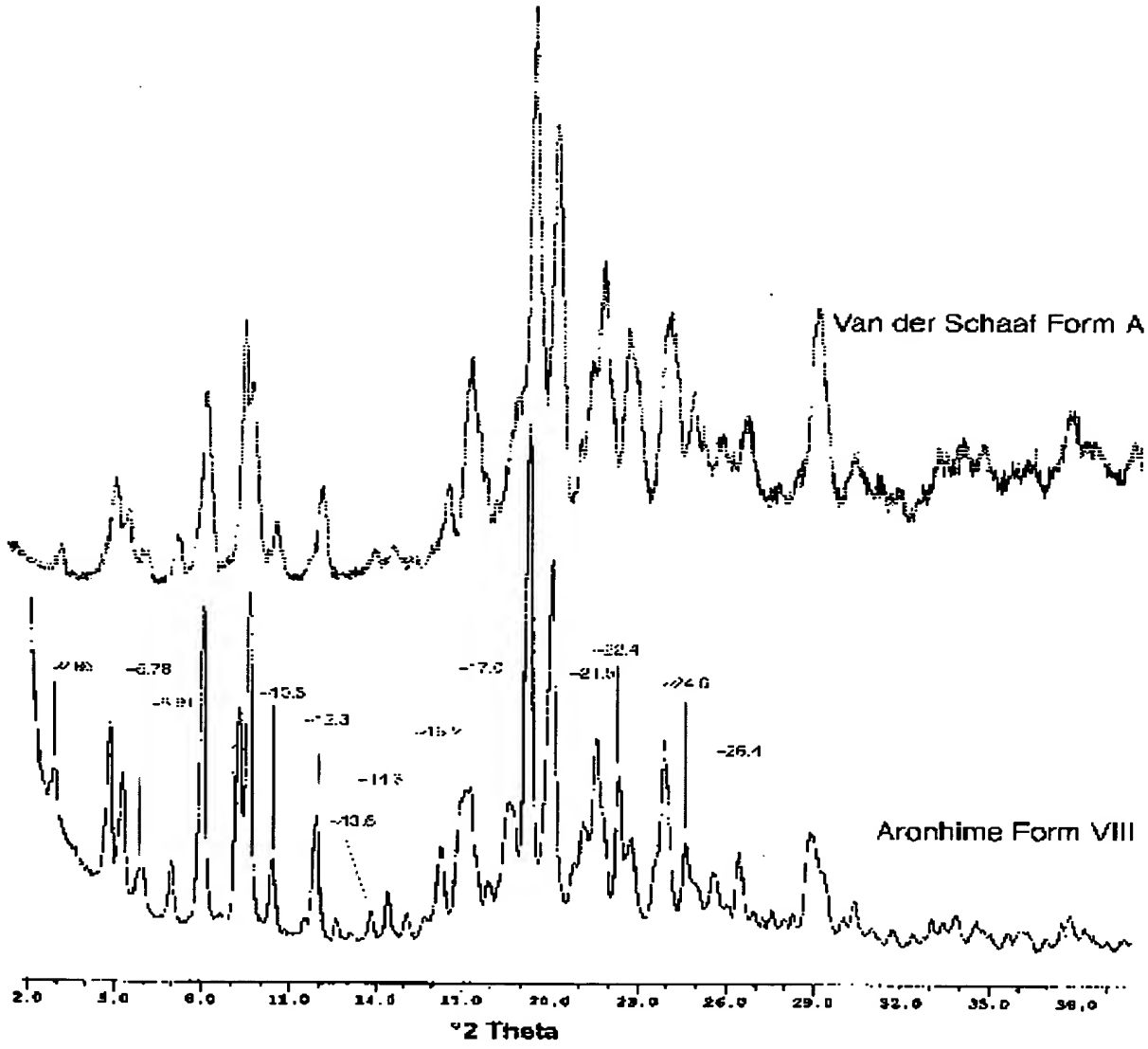
Van der Schaaf Form A
-6.78
-10.5
-17.0
-22.4
-21.5
-24.0
-26.4
Aronhime Form VIII
2.0
6.0
11.0
26.0
29.0
32.0
35.0
°2 Theta

Figure 2

VI. Claim 148 of the Aronhime application corresponds exactly to the proposed count and claims 147 and 149-155 correspond substantially to the proposed count

The proposed count is directed to the same subject matter as claim 148. The proposed count differs from claim 148 only in that the proposed count has been rewritten in independent form. Since the proposed count and claim 148 are directed to the same subject matter, claim 148 is the "same as" the proposed count and thus defines the same patentable invention as the proposed count according to 37 C.F.R.§1.601(n). Accordingly, claim 148 corresponds to the proposed count.

Claim 147 is directed to the same crystalline form of atorvastatin as the proposed count and, in part (a), recites the same X-ray diffraction peaks as are recited in the proposed count. Accordingly, claim 147 corresponds to the proposed count.

Claims 149-155 either narrow claim 148 by specifying additional PXRD characteristics or identify Form VIII by alternative X-ray characteristics. All of the X-ray characteristics of claims 149-155 are inherent in the subject matter of the proposed count because the proposed count defines a unique crystalline form of atorvastatin hemi-calcium. Therefore, claims 149-155 should be designated as corresponding to the proposed count, as each of those claims corresponds substantially to the count since each of these claims defines the same crystalline form of atorvastatin as the count.

VII. The two-way test is satisfied

The Court of Appeals for the Federal Circuit has approved the U.S. Patent and Trademark Office's practice of applying a "two way" test for determining whether an interference-in-fact exists (Eli Lilly & Co. v. Board of Regents of the University of Washington, 334 F3d 1264, 67 USPQ2d 1161 (Fed. Cir. 2003)). Under the two way test, an interference-in-fact exists between Party A and Party B if the claimed invention of Party A anticipates or renders obvious the claimed invention of Party B **and** the claimed invention of Party B anticipates or renders obvious the claimed invention of Party A (see Eli Lilly, at 334 F3d 1269, 67 USPQ2d 1165).

Under the two way test, an interference exists between claims 147-155 of the present application and claim 6 of the Byrn patent. As discussed above, the proposed count is merely claim 148 of the present application drafted in independent form. Accordingly, the subject matter of the count is identical to that of claim 148. The discussion above demonstrates that claim 6 of the Byrn patent and the count are directed to the same subject matter, *viz.*, the same crystalline form of atorvastatin. Since the count and claim 148 are directed to the same subject matter, and the count and claim 6 are directed to the same subject matter, it follows that claim 6 and claim 148 are directed to the same subject matter.

Since claim 6 of the Byrn patent and claim 148 of the Aronhime application are directed to the same subject matter, then claim 6, were it prior art, would anticipate claim 148 **and** claim 148, were it prior art, would anticipate claim 6. Accordingly, the two way test is satisfied.

By similar reasoning, since claim 2 of the Van der Schaaf application is also directed to the same crystalline form of atorvastating as claim 148 of the present application and claim 6 of the Byrn patent, then claim 2 of the Van der Schaaf application also satisfies the two way test with respect to either claim 148 of the present application or claim 6 of the Byrn patent.

VIII. 35 U.S.C. §135(b)(1) and (b)(2)

The requirements of 35 U.S.C. §135(b)(1) and (b)(2) are satisfied because the Byrn patent issued August 12, 2003, U.S. Patent Application Serial No. 10/456,046 was published March 18, 2004 (as US2004/0054193), the Van der Schaaf application has not yet been published[2], and claims 147-155 of the present application were filed on July 28, 2003. Moreover, Form VIII atorvastatin, the subject matter of claims 147-155, was claimed in the claims as filed of the present application and of the priority applications.

IX. The present application is entitled to the benefit of all of its priority applications for the invention defined by the count

U.S. Provisional Patent Application Serial No. 60/250,072, filed November 30, 2000, discloses the preparation of Form VIII atorvastatin at Examples 1-6, pages 9-11 and claims

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[2] U.S. Patent Application Serial No. 10/130,197 (the parent of the Van der Schaaf application) was published June 19, 2003 (as US2003/0114686).

Form VIII at claims 1-3.

Claim 1 recites the same X-ray diffraction peaks as are recited in the proposed count. Accordingly, the present application is entitled to the benefit of U.S. Provisional Patent Application Serial No. 60/250,072.

U.S. Provisional Patent Application Serial No. 60/267,897, filed February 9, 2001, discloses the preparation of Form VIII atorvastatin at Examples 1-3, pages 9-10 and claims Form VIII at claims 1 and 2. Claim 1 recites the same X-ray diffraction peaks as are recited in the proposed count. Accordingly, the present application is entitled to the benefit of U.S. Provisional Patent Application Serial No. 60/267,897.

U.S. Provisional Patent Application Serial No. 60/281,872, filed April 5, 2001, discloses the preparation of Form VIII atorvastatin at Examples 4-6, pages 17-19 and claims Form VIII at claims 13 and 14. Accordingly, the present application is entitled to the benefit of U.S. Provisional Patent Application Serial No. 60/281,872.

U.S. Provisional Patent Application Serial No. 60/312,144, filed August 13, 2001, discloses the preparation of Form VIII atorvastatin at Examples 4-8, pages 21-23 and claims Form VIII at claims 15 and 16. Accordingly, the present application is entitled to the benefit of U.S. Provisional Patent Application Serial No. 60/312,144.

U.S. Provisional Patent Application Serial No. 60/326,529, filed October 1, 2001, discloses the preparation of Form VIII atorvastatin at Examples 4-10, pages 24-26 and claims Form VIII at claims 21 and 22. Accordingly, the present application is entitled to the benefit of U.S. Provisional Patent Application Serial No. 60/326,529.

X. The inteference should be declared with both the present application and the Van der Schaaf application

The present application and the Van der Schaaf application are currently both assigned to the same entity, Teva Pharmaceutical Industries Ltd. Nevertheless the Applicants believe there is good cause under 37 C.F.R.§602(a) why an interference should be declared involving those two applications.

Barton v. Adang, 162 F3d 1140, 49 USPQ2d 1128(Fed. Cir. 1998) held that an interference should be permitted to continue with both commonly-owned inventions involved *until the count is definite and discovery completed.* In Barton, the Federal Circuit found that

the good cause exception of 37 C.F.R.§602(a) was satisfied where two of the three inventions to an interference were commonly owned. In Barton, an interference was declared between two applications and an issued patent. Early in the proceedings Monsanto, the owner of one of the applications in the interference, acquired the other involved application.

Because the two applications to the interference had become commonly owned, the U.S. Patent and Trademark Office (USPTO) had applied 37 C.F.R.§602(a) and required Monsanto to make an election between the applications. After the interference had concluded, Monsanto appealed this requirement to the Federal Circuit. Monsanto argued that at the time of the election there was good cause to continue the interference with both of its applications because (1) the count itself was still subject to change by preliminary motion, and (2) the nature of the inventions involved made determining priority dates difficult.

The Federal Circuit agreed with Monsanto that the good cause exception was satisfied:

> Therefore, at the time that Monsanto was forced to make an election . . . it was not clear what the content of the final count would be or what proofs on dates of conception and reduction to practice [the other party] would seek to establish. Also, if the final count as decided by the Board excluded subject matter disclosed in [the abandoned application], but not [the chosen application], Monsanto loses arguably patentable subject matter by early dismissal of [the abandoned application].[3]

For these reasons, the Federal Circuit ordered that the interference be continued with both commonly-owned applications involved *until the preliminary motions to finalize the count were decided and discovery complete.*

As was the case in Barton, the owner of the present application faces an interference between two competing applications and a patent where the two applications are commonly owned. Like Monsanto in Barton, the owner of the present application does not yet know the final count and there has not been discovery. The owner of the present application cannot currently know which of its applications will better support the final subject matter of the count or the eventually relevant priority dates. Under Barton, the owner of the present application should be allowed to involve both of its applications in the interference until the count is finalized and discovery completed.

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[3] 162 F3d at 1146, 49 USPQ2d 1134.

The only apparent distinction between this case and Barton involves timing – Monsanto became a common owner during an interference, while the owner of the present application is a common owner before an interference has been declared. This is a distinction without a difference for at least two reasons. First, the timing of common ownership does not change the fact that the owner of the present application still faces the exact same problems that Monsanto did in Barton – an indefinite count and very little information about the opponent's priority claim. Second, 37 C.F.R. §602(a) states that "[u]nless good cause is shown, an interference shall not be *declared or continued* . . .." The regulation appears to make no distinction between interference declaration and continuation, and the good cause exception applies to both situations. It follows that what constitutes good cause for continuation of an interference should also apply to its initial declaration.

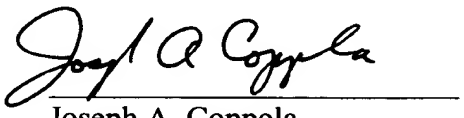
The Examiner is hereby notified of commonly-assigned unpublished U.S. Patent Application Serial No. 10/370,897, which discloses additional crystalline forms of atorvastatin hemi-calcium. Applicants have compared those forms to the count and found that they do not meet the limitations of the count.

CONCLUSION

Accordingly, it is respectfully requested than an interference be declared between the present application, the Byrn patent, the Byrn application, and the Van der Schaaf application.

Respectfully Submitted,

Dated: JULY 28, 2004



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